

## § 152.97

## 40 CFR Ch. I (7–1–14 Edition)

§152.115(a), any registration that is approved based upon a data gap claim shall be conditioned on the submission of the data no later than the time that the data are required to be submitted for similar products already registered.

(2) Notwithstanding paragraph (c)(1) of this section, the Agency will not approve an application if it determines that the data for which a data gap claim has been made are needed to determine if the product meets the requirements of FIFRA sections 3(c)(5) or (7).

[79 FR 6826, Feb. 5, 2014]

### **§ 152.97 Rights and obligations regarding the Data Submitters List.**

(a) Each original data submitter shall have the right to be included on the Agency's Data Submitters List.

(b) Each original data submitter who wishes to have his name added to the current Data Submitters List must submit to the Agency the following information:

(1) Name and current address.

(2) Chemical name, common name (if any) and Chemical Abstracts Service (CAS) number (if any) of the active ingredients(s), with respect to which he is an original data submitter.

(3) For each such active ingredient, the type(s) of study he has previously submitted (identified by reference to data/information requirements listed in part 158 of this chapter), the date of submission, and the EPA registration number, file symbol, or other identifying reference for which it was submitted.

(c) Each applicant not already included on the Data Submitters List for a particular active ingredient must inform the Agency at the time of the submission of a relevant study whether he wishes to be included on the Data Submitters List for that pesticide.

[79 FR 6826, Feb. 5, 2014]

### **§ 152.98 Procedures for transfer of exclusive use or compensation rights to another person.**

A person who possesses rights to exclusive use or compensation under FIFRA section 3(c)(1)(F) may transfer such rights to another person in accordance with this section.

(a) The original data submitter must submit to the Agency a transfer document that contains the following information:

(1) The name, address and state of incorporation (if any) of the original data submitter (the transferor);

(2) The name, address and state of incorporation (if any) of the person to whom the data rights are being transferred (the transferee);

(3) Identification of each item of data transferred including:

(i) The name of the study or item of data;

(ii) Whether the study is an exclusive use study, and, if so, when the period of exclusive use protection expires;

(iii) The name of the person or laboratory that conducted the study;

(iv) The date the study was submitted to the Agency;

(v) The EPA document number assigned to the item of data (the Master Record Identification Number or Accession Number), if known. If not known, the EPA administrative number (such as the EPA Registration Number, petition number, file symbol, or permit number) with which the item of data was submitted, such that the Agency can identify the item of data.

(vi) A statement that the transferor transfers irrevocably to the transferee all rights, titles, and interest in the items of data named;

(vii) A statement that the transferor and transferee understand that any false statement may be punishable under 18 U.S.C. 1001; and

(viii) The names, signatures and titles of the transferor and transferee, and the date signed.

(b) In addition, the original data submitter must submit to the Agency a notarized statement affirming that:

(1) The person signing the transfer agreement is authorized by the original data submitter to bind the data submitter;

(2) No court order prohibits the transfer, and any required court approvals have been obtained; and

(3) The transfer is authorized under Federal, State, and local law and relevant corporate charters, bylaws or partnership agreements.

(c) The Agency will acknowledge the transfer of the data by notifying both

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transferor and transferee, and will state the effective date of the transfer. Thereafter the transferee will be considered to be the original data submitter of the items of data transferred for all purposes under FIFRA section 3(c)(1)(F), unless a new transfer agreement is submitted to the Agency.

[49 FR 30903, Aug. 1, 1984, as amended at 73 FR 75595, Dec. 12, 2008]

### § 152.99 Petitions to cancel registration.

An original data submitter may petition the Agency to deny or cancel the registration of a product in accordance with this section if he has submitted to the Agency a valid study which, he claims, satisfies a data requirement that an applicant purportedly has failed to satisfy.

(a) *Grounds for petition.* (1) If an applicant has offered to pay compensation to an original data submitter of a study (either specifically or by filing a general offer to pay statement), the original data submitter may petition the Agency to deny or cancel the registration to which the offer related on any of the following grounds:

(i) The applicant has failed to participate in an agreed-upon procedure for reaching an agreement on the amount and terms of compensation. The petitioner shall submit a copy of the agreed-upon procedure and describe the applicant's failure to participate in the procedure.

(ii) The applicant has failed to comply with the terms of an agreement on compensation. The petitioner shall submit a copy of the agreement, and shall describe how the applicant has failed to comply with the agreement.

(iii) The applicant has failed to participate in an arbitration proceeding. The petitioner shall submit evidence of such failure.

(iv) The applicant has failed to comply with the terms of an arbitration decision. The petitioner shall submit a copy of the arbitration decision, and describe how the applicant has failed to comply with the decision.

(2) When no offer to pay has been made, the petitioner shall state in his petition the basis for the challenge, and describe how the failure of the applicant to comply with the procedures

of this subpart has deprived him of the rights accorded him under FIFRA section 3(c)(1)(F). Possible grounds for challenge include, but are not limited to, the following:

(i) The applicant has failed to list a data requirement applicable to his product, or has failed to demonstrate compliance with all applicable data requirements.

(ii) The applicant has submitted or cited a study that is not valid.

(iii) The applicant has submitted or cited a study that does not satisfy the data requirement for which it was submitted or cited.

(iv) The applicant has falsely or improperly claimed that a data gap existed at the time of his application.

(v) The applicant has submitted or cited a study originally submitted by the petitioner, without the required authorization or offer to pay.

(b) *Procedure for petition to the Agency—*(1) *Time for filing.* A petition under paragraph (a)(1) of this section may be filed at any time that the circumstances warrant. A petition under paragraph (a)(2) of this section must be filed within one year after the Agency makes public the issuance of the registration.

(2) *Notice to affected registrant.* At the same time that the petitioner files his petition with the Agency, the petitioner shall send a copy to the affected applicant or registrant by certified mail or by any other method that provides evidence of delivery. The affected applicant or registrant shall have 60 days from the date of receipt of the petition to submit written comments to the Agency.

(c) *Disposition of petitions.* The Agency will consider the material submitted by the petitioner and the response, if any, by the affected applicant or registrant.

(1) If the Agency determines that the petition is without merit, it will inform the petitioner and the affected applicant or registrant that the petition is denied. Denial of a petition is a final Agency action.

(2) If the Agency determines that an applicant has acted in any way described by paragraph (a)(1) of this section, the Agency will notify the petitioner and the affected applicant or